



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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HEI-35

URG
6/12/98

Food and Drug Administration

555 Winderley Place, Suite 200

Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Re: Customs Entry No. R19-0019120-5
Blackberries and French Beans

WARNING LETTER

FLA-98-53

June 10, 1998

Michael Parr, President
Gelco International, S.A.
1925 N.W. 66th Avenue
Building #2141
Miami, Florida 33126

Dear Mr. Parr:

The Food and Drug Administration (FDA) attempted to examine a shipment of blackberries (207 flats) and french beans (346 cartons) offered for entry into the United States by your firm on May 24, 1998, under the above referenced entry number, and determined that 96 flats of blackberries and 100 cartons of french beans were not available for FDA examination.

Regulation 1.90, Title 21, Code of Federal Regulations (21 CFR 1.90), requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We have requested the U.S. Customs Service (Customs) to order redelivery of these products (copy enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

Please notify this office in writing within fifteen (15) working days after receipt of this letter of the specific steps you have taken to correct the violations, including an explanation of each step being taken to prevent recurrence. In addition, you should inform Customs and FDA if and when redelivery is accomplished.

Your written reply should be addressed to the Food and Drug Administration, Attention:
Paul R. Bagdikian, Compliance Officer, P.O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

A handwritten signature in black ink, appearing to read "Douglas D. Tolen". The signature is fluid and cursive, with the first name "Douglas" and last name "Tolen" clearly distinguishable.

Douglas D. Tolen
Director, Florida District

Enclosure

cc: District Director
U.S. Customs Service
P.O. Box 52-3215
Miami, Florida 33152-3215

bcc:

HFR-SE200/EI JKT

HFR-SE240/ERA/LGL JKT/WL FILE

HFR-SE275/MIA-RP/JAB/PRB/MRC

HFI-35 (PURGED)

HFA-224

HFC-210 (CFN #

HFC-170/DIOP

DRAFT: PRB 6/4/98

rec'd: 6/10/98

redraft: 6/10/98 mrj

final: 6/11/98

A handwritten signature in black ink, appearing to be "E. R. J.", is written over the word "final" in the distribution list.